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09/694,293	10/23/2000	Stephen T. Kuehn	S16.12-0101	1653

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[REDACTED] EXAMINER

NGUYEN, VICTOR

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

3731

DATE MAILED: 07/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/694,293	KUEHN ET AL.
	Examiner Victor X Nguyen	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 October 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 October 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the following figures 16, 20d, 21, 25 and a reference sign “348 in figure 15g” does not include as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 13 in line 6 recites the limitation “an actuating element”. The claim is indefinite because it is unclear what the applicant is claiming as the invention.

5. Claim 24 contains the trademark/trade name “Elgiloy, MP35N, Nitinol”. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the

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goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a type of a heart valve repair instrument and, accordingly, the identification/description is indefinite. See MPEP 2173.05(u).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13 are rejected under 35 U.S.C. 102 (e) as being anticipated by Laufer et al (U.S. 5,810,847).

Regarding claim 1, notes Laufer Figures 2,4 read on a surgical instrument (15) comprising at-least one pair of arms (40, 42), wherein the arms (40, 42) pivot from one orientation to a gripping position (col 5, lines 35-45), wherein a portion of each pair arms (40, 42) is directed toward each other.

Regarding claims 2 and 3, notes Laufer Figs 2, 4 read on a surgical instrument (15), wherein the arms (40, 42) flex to a core (53), wherein the surgical instrument (15) has a gripping position (col 5, lines 35-45), and wherein one of the arms (40, 42) includes a projection for gripping a valve (col 5, lines 35-45).

Regarding claims 4 and 5, notes Laufer Figs 8-10 read on a kit having a catheter (82), a fastener applicator (80, 86, 87). The catheter (82) has a suitable dimension for deployment and insertion into a human heart (col 7, lines 42-67). Furthermore, the pair arms (40, 42) comprise the gripping elements (col 5, lines 35-45).

Regarding claims 6, 7, notes Laufer Figs 8-10 read on a kit, wherein a pair of arms (40, 42) comprise a pointed tip (56 is considered a tip) and a clasp (55 is considered a clasp) that engage each other in the gripping position (col 5, lines 35-45). The arms (40, 42) flex to a low position to fit within the catheter (82).

Regarding claims 8, 9, notes Laufer Figs 2-3 read on a kit, wherein the surgical instrument (15) comprises a shaft (16) and a sleeve (not labeled) that slides over the shaft (16), wherein one member of the pair of arms (40,42) slides along the shaft (16) with the sleeve (not labeled) engaging the sliding arms (40,42) to constrain their movement along the shaft (16). The arms (40,42) can slide along the shaft (16) between a low position for fitting within the catheter (82).

Regarding claims 10, 11, notes Laufer Figs 2-3 read on a kit, wherein the arms (40,42) pivot between a low position and an unconstrained extended position. The fastener applicator (80, 86, 87) comprises a shaft (16) and the fastener (80, 86, 87) holds the leaflet fastener on the shaft (16).

Regarding claims 12, 13, note Laufer Figs 2-3 read on a kit, wherein the fastener applicator (80, 86, 87) comprises a shaft (16) and a latch (50, 54) that releasably holds the surgical device (15) on the shaft (16). The kit comprises a catheter (82), a fastener applicator (80, 86, 87). The catheter (82) has a suitable dimension for deployment and insertion into a human heart (col 7, lines 42-67).

The functional language drawn to intended use, "Capable of fastening two adjacent leaflets" can not serve to distinguish over the prior art which includes all of the structural elements called for in the claims and can thus inherently perform in the same manner as the claim invention.

Claims 14-17 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bergman et al (U.S. 5,181,919).

Regarding claim 14, note Bergman Figs 1,2,3 read on a surgical device (10) comprising a ring (col 1, lines 6-30) and an applicator (col 1, lines 1-55), wherein the ring (col 1, lines 6-30) comprises two pointed shafts (16, 17) and wherein the applicator (col 1, lines 1-55) can apply a force to the ring (col 1, lines 6-30) to deform the ring (col 1, lines 6-30) to bring the points of the shafts (16, 17) toward each other. The ring (col 1, lines 6-30) and the applicator (col 1, lines 1-55) have an appropriate size for placement within a chamber of a human heart (col 1, lines 1-57).

Regarding claims 15, 16, note Bergman Figs 1,2,3 read on a surgical device (10), wherein the ring (col 1, lines 6-30) comprises a curved tube (11, col 6, lines 4-22) extending from one pointed shaft (16, 17) into which the second pointed shaft (16, 17) extends. The ring (col 1, lines 6-30) further comprises a spring (15) within the tube (11, col 6, lines 4-22), wherein the pointed shaft (16, 17) and a lock (col 7, lines 30-41) that can hold the second pointed shaft (16, 17).

within the tube (11, col 6, lines 4-22) in a locked position, and wherein the force applicator (col 1, lines 1-55) can apply a force to release the lock (col 7, lines 30-41).

Regarding claim 17, note Bergman Figs 1,2,3 read on a surgical device (10), wherein the two pointed shaft (16, 17) extend from a notch that is a weak point at which the ring (col 1, lines 6-30) can be deformed to direct the pointed shafts (16, 17) toward each other.

Claims 18-22, 24-29 are rejected under 35 U.S.C. 102 (b) as being anticipated by King et al (U.S. 3,874,388).

Regarding claim 18, note King Figs 2a, 3a, 7, 8 read on an instrument comprising a shaft (2 is considered a shaft), a cap (8, fig 8), a gripper (Figs 6, 7, col 7, lines 37-68) and a flexible rod (3 is considered a rod), wherein the gripper (Figs 6, 7, col 7, lines 37-68) comprises a plurality of arms (52, col 7, lines 60-67) radiating from a pivot (84, 294) with each arm (52, col 7, lines 60-67) having a spike, wherein the cap (8, fig 8) is located distal to the pivot (84, 294) and the pivot (84, 294) is located distal to the shaft (2), and wherein the flexible rod (3) connects to the cap (8, fig 8) to provide for movement of the cap (8, fig 8) relative to the gripper (Figs 6, 7, col 7, lines 37-68) and the shaft (2) by pulling the flexible rod (3). The cap (8, fig 8) has an opening that can be inserted over the pivot (84, 294) to lock the arms (52, col 7, lines 60-67) in a closed position.

Regarding claims 19, 20, note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the arms (52, col 7, lines 60-67) connected by a resilient web (col 6, lines 31-54), wherein the pivot (84, 294) is formed from the spring metal (col 7, lines 59-68; col 8, lines 1-7).

Regarding claims 21, 22, note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the arms (52, col 7, lines 60-67) comprises two pairs of arms (Fig 7, 91), wherein the pairs of arms

(Fig 7, 91) are connected by a resilient web (col 6, lines 31-54), and wherein the web (col 6, lines 31-54) is covered with fabric (col 6, lines 49-68).

Regarding claims 25, 26, note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the pivot (84, 294) comprises a hinge (col 6, lines 14-50), wherein the hinge (col 6, lines 14-50) comprises a spring (col 6, lines 14-50; col 8, lines 1-18).

Regarding claim 27, note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the arms (52, col 7, lines 60-67) are biased to an extended position due to the forces at the pivot (84, 294) and further comprising strands (col 8, lines 36-67) connect the shaft (2) with the arms (52, col 7, lines 60-67).

Regarding claims 28, 29 note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the rod (3) has a disengaging mechanism that connects the cap (8, fig 8) to the rod (3). The cap (8, fig 8) comprises a ridge (291, 291') and the gripper (Figs 6, 7, col 7, lines 37-68) comprise a bump (col 8, lines 19-68) positioned to engage the ridge (291, 291') in the locked position.

Regarding claim 30, note King Figs 2a, 3a, 7, 8 read on an instrument comprising a cap (8, fig 8) and a gripper (Figs 6, 7, col 7, lines 37-68) comprises a plurality of arms (52, col 7, lines 60-67) radiating from a pivot (84, 294), wherein each arm has a spike, and wherein the pivot (84, 294) is inserted within an opening in the cap (8, fig 8) to lock the arms (52, col 7, lines 60-67).

Regarding claims 31, 32 note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the cap (8, fig 8) comprises a locking mechanism that engages the gripper (Figs 6, 7, col 7, lines 37-68) in a locked position. The cap (8, fig 8) comprises a slot (col 7, lines 60-68, col 8, lines 1-7), and wherein the gripper (Figs 6, 7, col 7, lines 37-68) is held by the stops within the slot (col 7,

lines 60-68, col 8, lines 1-7) such that the gripper (Figs 6, 7, col 7, lines 37-68) can slide within the slot to alter the extension of the gripper (Figs 6, 7, col 7, lines 37-68) with the stops to prevent the separation of the cap cap (8, fig 8) and the gripper (Figs 6, 7, col 7, lines 37-68).

Regarding claim 33, note King Figs 2a, 3a, 7, 8 read on an instrument, wherein the rod (3) has a disengaging mechanism that permits the rod (3) to releasably hold the cap (8, fig 8).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103 (a) as being unpatentable over King et al (3,874, 388).

King discloses the claimed invention except the memory metal comprises a nickel alloy. It would have been obvious matter of design choice to disclose the memory metal comprises a nickel alloy, since the applicant has not disclosed that the useful of making the memory metal comprises a nickel alloy solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any equivalent material.

Conclusion

8. The prior made of record and not relied upon is considered pertinent to applicant's disclosure.

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U.S. Pat. No. 5,976,164 to Bencini et al

U.S. Pat. No. 5,976,164 to Detweilwer

U.S. Pat. No. 5,478,353 to Yoon

U.S. Pat. No. 5,891,162 to Sugarbaker

U.S. Pat. No. 6,120,513 to Bailey et al

U.S. Pat. No. 5,425,738 to Gustafson

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898.

The examiner can normally be reached on M-F (8-4.30 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

Vn
July 25, 2002

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